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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,220

03/22/2004

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/805,220	Applicant(s) YAMAGUCHI ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,20-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,20-22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed September 28, 2007 is acknowledged and entered. Claims 17, 20-22 and 24-26 are pending and under examination.

Claims Summary and Interpretation

2. The claims are drawn to a method for detecting Borna Disease Virus (BDV) infection by detecting IgM and/or IgG antibodies to BDV antigen polypeptides. The method comprises:

(a) providing a support sensitized with a p10 BDV synthetic antigen polypeptide, and a p24 or p40 BDV antigen polypeptide; or, a support sensitized with p10, p24 and p40;

(b) reacting the support with a sample that is suspected of containing anti-BDV antibodies;

(c) detecting both IgM and IgG antibody, thus detecting infection.

Specifically, the polypeptide from the p24 region is SEQ ID NO: 1. The polypeptide from the p40 region is SEQ ID NO: 3. The polypeptide from the p10 region is SEQ ID NO: 8.

Claim Objections

3. Claims 17, 20-22 and 24-26 are objected to for minor informalities:
 - All claims recite a typographical error, "BVD", instead of the correct acronym for Borna Disease Virus (BDV).
 - Claims 20-22 and 25-26 recite claim preambles that do not use consistent language with the independent claims from which they depend. Claims 17 and 24 recite, "A method of

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detecting Borna disease virus (BDV) infection". However, dependent claims 20-22 and 25-26 recite, "The method for detecting an antibody".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 20-22 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The claims are drawn to a method of detecting BDV infection in a subject. The specification as a whole does not contemplate the detection of infection, rather, the detection of antibodies that bind BDV. The specification, in each described embodiment, appears to only contemplate the detection of IgM and IgG for purposes of assisting in the examination of a disease caused by BDV. However, the specification does not appear to teach the detection of BDV disease by solely detecting IgM and IgG.

5. (*New Rejection*) Claims 17, 20-22 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting antibodies that bind BDV, does not reasonably provide enablement for detecting an infection with BDV

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wherein the infection is either an active infection or a past infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The breadth of the claims encompasses the detection of both an acute infection and a past infection. The nature of the invention is the detection of IgM and IgG as indicators of infection with BDV. The level of skill in the art is high, evidenced by the instant inventors and those authors cited in the literature references of record.

The state of the art acknowledges the existence of serological tests that detect the presence of IgM and IgG (Carbone, K.M., *Clin. Micro. Rev.*, 2001, 14(3):513-527, "Carbone", see page 516, first column, second full paragraph). Carbone discloses that "a significant increase in the titer of virus-specific IgG from the acute-phase to the convalescent phase serum sample is indicative of infection", page 516, first column, second full paragraph, last sentence. Carbone also teaches that viruses in general may or may not be present in subjects that have tested positive for anti-serum because some viruses are cleared while others persist. Whether BDV persists or is cleared in humans is unknown, and Carbone concludes that the detection of anti-BDV antibodies does not relate to the presence or clearance of BDV in humans (page 516, top of second column). The state of the art also speaks to the low level of predictability in the art with regard to the meaning of the detection of IgM and IgG. Theoretically, the IgM and IgG test should be reasonably indicative of an active infection, however, as taught by Carbone, the lack of knowledge relating to the ability of BDV to persist or be cleared in humans renders the detection of these antibodies useless in the determination of an active infection or a past infection.

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The guidance and working examples provided in the specification do not appear to even contemplate the detection of infection, rather, the specification is focused on the detection of antibodies (see New Matter rejection above).

Therefore, in view of the breadth of the claims, the state of the art, the high level of skill in the art, the low level of predictability, the limited guidance provided in the specification and the lack of working examples (detection of acute/past infection), it would require undue experimentation for one of skill in the art to practice the methods as claimed.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 20-22 and 24-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi *et al.* (*Ann. Clin. Biochem.* 2001, 38:348-355, "Yamaguchi"), in view of Watanabe *et al.* (*J. Vet. Med. Sci.*, 2000, 62(7):775-778, "Watanabe"), as evidenced by Planz *et al.* (*Journal of Virology*, 1999, 73:6251-6256, "Planz") and further in view of Hatalski *et al.* (*Journal of Virology*, February 1995, 69(2):741-747, "Hatalski"), and Carbone, K.M. (*Clin. Micro. Rev.*, 2001, 14(3):513-527, "Carbone"). All claims are summarized above, and the rejection is of record.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive argument is primarily directed to the following:

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Applicant argues that neither Yamaguchi, Hatalski, nor Watanabe disclose a p10 BDV synthetic antigen polypeptide as instantly claimed. Applicant argues that Planz and Carbone do not provide the deficiencies of the other references. In response to Applicant's arguments, the Office does not give patentable weight to the term "synthetic" in this situation. That the polypeptide is synthetic does not change the polypeptide itself because it still consists of the same amino acids as the natural polypeptide. The term "synthetic" merely indicates the process by which the product is made. Because the synthetic p10, p24 and p40 polypeptides are expected to be the same, or functional equivalents of natural or recombinant p10, p24 and p40, the invention remains obviated by the teachings of record. Applicant has not demonstrated that antibodies that bind to synthetic p10, p24 and p40 are any different than antibodies that bind to natural or recombinant p10, p24 and p40. The specification's teachings regarding the synthetic polypeptides are limited to paragraph [0127] of the US Patent Application Publication, which discloses that synthetic polypeptides can be made. The specification does not disclose that synthetic polypeptides are expected to behave any differently than natural or recombinant polypeptides. Therefore, the term "synthetic" does not distinguish over the prior art of record.

Conclusion

7. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 11-27-2007
Primary Examiner, TC1600